

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 9516-335-228	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/28742	International filing date (day/month/year) 03 September 2004 (03.09.2004)	Priority date (day/month/year) 05 March 2004 (05.03.2004)	
International Patent Classification (IPC) or national classification and IPC IPC: A61K 314-35 USPC: 514/417			
Applicant CELEGENE CORPORATION			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 05 October 2005 (05.10.2005)		Date of completion of this report 30 March 2006 (30.03.2006)	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Sreeni Padmayabhan Telephone No. 571-272-0600	

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/28742

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
- pages 1-68 as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the claims:
- pages 69-74 as originally filed/furnished
- pages* NONE as amended (together with any statement) under Article 19
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☒ the drawings:
- pages NONE as originally filed/furnished
- pages* NONE received by this Authority on _____
- pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/28742

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
1. Statement		
Novelty (N)	Claims <u>14-17</u>	YES
	Claims <u>1-13 and 18-27</u>	NO
Inventive Step (IS)	Claims <u>14-17</u>	YES
	Claims <u>1-13 and 18-27</u>	NO
Industrial Applicability (IA)	Claims <u>1-27</u>	YES
	Claims <u>NONE</u>	NO
2. Citations and Explanations (Rule 70.7)		
<p>Claims 1-12, 24-27 lack novelty under PCT Article 33(2) as being anticipated by Tobinick (US 6, 623,736). Tobinick discloses a method of treating central nervous system disorder such as Alzheimer's disease by administering antagonists of cytokines. See column 1, lines 9-20, lines 56-60. A combination therapy is also disclosed. See column 9, lines 5-35. Thus Tobinick anticipates instant claims 1-12, 24-27.</p> <p>Claims 1-4, 7-8, 13, 18-19, and 24-26 lack novelty under PCT Article 33(2) as being anticipated by Muller (WO 97/08143). Muller discloses a method of treating central nervous system disorder such as multiple sclerosis by administering cytokine inhibitors of the instant invention formula (I). See page 1, line 5, page 3 line 30-page 4, line 7; page 5, lines 15-page 7. Thus Muller anticipates instant claims 1-4, 7-8, 13, 18-19, and 24-26.</p> <p>Claims 1-8, 20-21, and 24-26 lack novelty under PCT Article 33(2) as being anticipated by Muller (WO 99/06041). Muller discloses a method of treating central nervous system disorder such as multiple sclerosis by administering cytokine inhibitors of the instant invention formula (II). See page 1, line 11; page 5 lines 30-33; page 7, lines 1-25. Thus Muller anticipates instant claims 1-8, 20-21, and 24-26.</p> <p>Claims 1-4, 7-8, and 22-26 lack novelty under PCT Article 33(2) as being anticipated by Schafer (WO 03/080048). Schafer discloses a method of treating disorders ameliorated by reduction of TNF-alpha by administering cytokine inhibitors of the instant invention formula (III). See page 1, and page 6. Thus Schafer anticipates instant claims 1-4, 7-8, and 22-26.</p> <p>Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.</p>		